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HOUSE ENERGY & COMMERCE COMMITTEE
21ST CENTURY CURES ROUNDTABLE: Spurring Innovation, Advancing Treatments, & Incentivizing Investment
HOSTED BY: The Honorable Gus Bilirakis

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Congressman Bilirakis, thank you for the opportunity to participate in today's 21st Century Cures roundtable discussion on spurring innovation, advancing treatments, and incentivizing investment. We are pleased that you are here in Tampa to host this discussion in your role as a member of the House Energy & Commerce Committee.

I am Dr. Glen Hortin, the clinical pathology medical director for the southeast region for Quest Diagnostics, the world's leading provider of diagnostic information services. I have worked at Quest Diagnostics since 2010, and I am one of more than 3,600 Quest Diagnostics employees here in Florida. Earlier in my career, I served as chief of clinical chemistry at the Department of Laboratory Medicine at the National Institutes of Health. I have also advised the Food and Drug Administration (FDA) as a member and chairman of the FDA's Immunology Devices Panel.

The diagnostic tests developed by America's clinical laboratories are absolutely essential to better healthcare. By some estimates, clinical laboratory tests guide more than 70% of medical decisions made by healthcare providers. The information provided by clinical lab tests helps physicians and other health professionals diagnose, treat, and monitor patients accurately and quickly.

For an example of the innovative nature of the clinical laboratory industry, consider personalized medicine. The term "personalized medicine" was introduced into the scientific and popular press in 1999. Over the last fifteen years, clinical laboratories have played a leading role in taking personalized medicine from concept to reality -- and patients with cancer, heart disease, HIV, and other conditions are living longer and enjoying better health because of it.

At the center of this healthcare revolution are genetic and genomic tests that identify the unique genetic profile of individual patients or their disease and allow physicians to tailor treatment to those unique characteristics. The result is earlier diagnosis and treatment, better prevention, and targeted therapy with fewer side

effects. Using the guidance from genetic tests, physicians can prescribe the right drug, at the right time, at the right dose.

This revolution in healthcare is far from over. In fact, it's just beginning – but whether it continues depends on whether public policy supports or undermines future scientific advances in diagnostic testing.

Right now, clinical laboratories are faced potentially with a complete upheaval in the regulatory and reimbursement environment for laboratory diagnostics. A new law enacted on April 1 of this year tasks the Centers for Medicare and Medicaid Services (CMS) with creating a new market-based payment system for laboratory testing covered under Medicare. Then just a few weeks ago, FDA announced that it intends to issue guidance under which it would regulate laboratory-developed tests (LDTs), despite the fact that laboratories are already subject to a comprehensive regulatory framework under the Clinical Laboratory Improvement Amendments (CLIA) and state law.

Each of these developments comes with a host of questions that need to be answered, and the answers to these questions will have an immense impact on the future of clinical laboratory diagnostics and the patients who rely on advanced diagnostics for better healthcare.

For nearly 50 years, the clinical laboratory industry has been primarily regulated by CMS under CLIA. Over the ensuing years, health care providers have ordered millions of LDTs for their patients with few problems, which suggests that regulation of LDTs under CLIA has effectively protected the public health.

Despite this record, the FDA announced late last month that it intends to publish guidance to regulate LDTs. We appreciate that Congressman Bilirakis and his colleagues on the House Energy & Commerce Committee included a provision in the Food and Drug Administration Safety and Innovation Act of 2012 whereby the agency must give Congress 60 days notice and a summary of any such guidance or regulation impacting LDTs. We hope the Committee will continue to pay close attention to this issue going forward.

The current regulatory scheme under CLIA affords laboratories the flexibility to develop tests quickly and to update them regularly as medicine advances, so that patients have access to the most current diagnostic testing science. This flexibility could be lost under FDA regulation.

Under CLIA, laboratories may continually update their tests to reflect scientific developments, as long as they appropriately validate and document test modifications. Under the FDA regulatory scheme, these modifications often would require supplemental filings and authorizations from FDA. Additional authorizations can take months to obtain, and in many cases, laboratories could not implement the modifications in the interim. In this way, the often-cumbersome

process of FDA regulation could hinder scientific progress in the diagnostic testing field.

Adding another layer of regulation to diagnostic testing will also add to healthcare costs. We hope the Committee will ask FDA whether the agency has undertaken a thorough economic analysis that considers the direct costs to clinical laboratories and the taxpayer, as well as the opportunity costs if additional regulation serves to stifle research in areas of unmet medical need.

On reimbursement, we urge the Committee to pay close attention to how CMS plans to implement the new market-based payment system for diagnostic tests covered by Medicare. The clinical laboratory industry generally supports this move to market-based reimbursement, included in the Protecting Access to Medicare Act of 2014, but our continued support depends on the legislation being implemented in a careful and collaborative fashion.

The way in which CMS defines the parameters, participants, methods, and timeframes for lab services payment rate and volume reporting will have a substantial impact on the rates that the Medicare program pays for clinical laboratory tests. Less obviously, it also could impact the rates paid by other government and commercial payors, since other payors often base their reimbursement levels on Medicare rates.

Decisions made during this process will have a major impact on the clinical laboratory industry and the patients we serve, and it is important that those decisions work to promote ongoing diagnostic innovations and protect access to critical lab testing for Medicare beneficiaries. By delivering innovative and higher quality diagnostics, we will be able to diagnose and prevent disease sooner, leading to lower costs and higher quality of care while saving lives. We know you share these goals, Congressman Bilirakis, by hosting this 21st Century Cures roundtable.

Thank you for your leadership, Congressman, and for the opportunity to participate in today's roundtable. I look forward to discussing these and other issues with you.